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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/032,239
Filing Date: December 21, 2001
Appellant(s): WEICKERT ET AL.

Michael J. Mazza
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 6, 2006 appealing from the Office action mailed July 14, 2004.

***(1)* Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent 5,965,156	Proffitt et al.	October 12, 1999
US Patent 6,077,543	Gordon et al.	June 20, 2000
US Patent 4,016,254	Seager	April 5, 1977
WO 97/03649	Staniforth	February 6, 1997

(9) Grounds of Rejection

Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 40, and 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al. (US 5,965,156), in view of Staniforth (WO 97/03649, IDS) and Gorden et al. (US 6,077543, IDS).

3. Proffitt et al. teaches an amphotericin liposome powder with diameters less than 2 um, which may be obtained through a spray drying of an acidified solution of amphotericin. The powders characterized as stable and less toxic. See, particularly, column 4, line 55 to column 7, line 35, and the claims. Further, it is well known that amphotericin B is useful for treating fungal infections. See, particularly, column 1, lines 30-45.

4. Proffitt et al. does not teach expressly a powder contains more than 30% by weight of amphotericin, which is for inhalation.

5. However, Staniforth teaches that powder composition for inhalation generally comprising high concentration of active ingredient, (e.g., 60% or higher by weight). See, the abstract. The optimal particle size for lung inhalation administration is 0.1 um to 5um and leucin is added as anti-adherent material. See, particularly, the abstract. Gordon et al. teaches that hydrophobic drugs for lung delivery, such as amphotericin B are known to be made into particles less than 5 um in size. See, particularly, column 1, lines 52-67, column 5, line 20 to column 6, lines 62.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition).

A person of ordinary skill in the art would have been motivated to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition) because Proffitt's method is known to provide stable amphotericin composition. Further, making a powder composition suitable for inhalation (i.e., with certain size of the particle) administration, or controlling degradation of the active ingredient during the process of making, is a matter of optimization of a result effective parameter, which is considered within the skill of the artisan, particularly in view of the fact that method of making such powders is well-known in the art (see Staniforth et al. and Gorden et al). See, In re Boesch

and Slaney (CCPA) 204 USPQ 215. Further, it would have been obvious to employ a known antifungal agent for treating fungal infection patient.

6. Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al. (US 5,965,156), in view of Staniforth (WO 97/03649, IDS) and Gorden et al. (US 6,077543, IDS) for reasons set forth above, and in further view of Seager et al.

7. Proffitt et al., Staniforth and Gorden et al. take together do not teach expressly the employment of aqueous suspension, wet milling and spray drying to make the powder.

8. However, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made to employ wet milling-spray drying technique for making a powder because such technique is well known in the art for making fine particles. See, e.g., column 8, line 66 to column 9, line 10.

(10) Response to Argument

9. In response to appellants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). One or ordinary skill in the art, possessing the knowledge disclosed in the cited references, would have seen the claimed invention obvious. Particularly, knowing the technique of making a stable polyene particles as disclosed by Proffitt, and the employment of amphotericin B for lung delivery, one of ordinary skill in the art would have combine the known knowledge of making polyene aerosol to arrive the claimed invention.

In response to appellants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found in the cited references and in the knowledge generally available to one of ordinary skill in the art.

Appellants further argue that the dry powder disclosed by Proffitt et al. is not suitable for lung delivery. The examiner contends that a prima facie case that the dry powder of Proffitt is not suitable for lung delivery has not been established on the record.

10. Further, it is noted that Proffitt teaches dried monohydrated stable powders. See, particularly, column 5, lines 26-43, and examples 1 in column 8. Therefore, Proffitt's method is suitable for make aerosol dried powder.

Furthermore, as to process recited in the claims, it is further noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see also MPEM 2113).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Shengjun Wang

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PRIMARY EXAMINER

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